



*Producers of Quality  
Nonprescription Medicines and  
Dietary Supplements for Self-Care*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

*Formerly Nonprescription Drug Manufacturers Association*

March 29, 1999 9:09 APR -5 12:19

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

RE: Docket Number 98P-0043: Food Labeling: Nutrition  
Labeling of Dietary Supplements on a "Per Day" Basis

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA), formerly the Nonprescription Drug Manufacturers Association (NDMA), is the 118-year-old trade organization representing the producers of quality dietary supplements and nonprescription medicines. CHPA members market major national brands and store brands of dietary supplements which would be affected by the above-referenced proposed rule,

CHPA submits these comments to FDA's proposal to amend its nutrition labeling regulations for dietary supplements to provide that the quantitative amount and the percent of Daily Value of a dietary supplement maybe voluntarily presented on a "per day" basis in addition to the required "per seining basis," if a recommendation is made on the label that the dietary supplement be consumed more than once per day.

CHPA supports FDA's proposal in response to the January 23, 1998 Citizen Petition from the Nutrilite Division of Amway Corp. In order to optimize the benefits and safety of dietary supplements recommended for use more than once a day, companies should be permitted to include information for the consumer about the quantitative amount of the Daily Value of each dietary ingredient to be consumed per day.

Further, the Association supports the agency in proposing that the information relating to "per day" labeling:

1. Should be allowed to appear on the label, at the manufacturer's discretion;
2. Should be in accordance with the requirements of § 101.36 (e), which pertains to the presentation of nutrition information, or the special labeling provisions for small and intermediate-sized packages in § 101.36(i)(2), with the appropriate redesignation of affected misting paragraphs in § 101;

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3. Should be based on a sample label in new § 101.36 (c)(1)(vii), which suggests a format for a dietary supplement label regarding information on both a "per serving" and "per day" basis, in order to help facilitate the interpretation of FDA's final rule;
4. Should be allowed on an interim basis prior to issuance of a final rule, because it is not misleading and it is useful to consumers to help them optimize product use.

In addition, CHPA supports the FDA proposal that the information should be presented in additional columns to the right of the "per serving" information with the use of appropriate headings as illustrated in the proposed rule, but only as a starting point when a company is voluntarily choosing to display such information. CHPA recommends that FDA add a provision that would allow companies to use a paragraph listing of this information under the statement in the Supplement Facts Box pertaining to "Serving Size," as follows by way of example:

<b>Supplement Facts</b>		
<b>Serving Size 1 Caplet</b>		
<b>Recommended Servings Per Day 3 Caplets</b>		
<b>(multiply per caplet amounts by 3 for per day amount)</b>		
	<b>Per Caplet</b>	
	<b>Amount</b>	<b>% Daily Value</b>
<b>Calcium (as calcium citrate)</b>	<b>500</b>	<b>50%mg</b>
<b>vitamin D (as cholecalciferol)</b>	<b>125 IU</b>	<b>31%</b>

Our reasons for suggesting this additional feature to FDA's proposed rule relates to our long-standing commitment to seeking enhancements to label readability, which is an important consumer healthcare product concern,

1. CHPA has spent this decade seeking ways to improve further the label readability of OTC medicines, working closely with the agency to define the format and label content of the OTC Information Panel so that it is consumer-friendly in appearance and use. An important aspect of label readability is type size. While we have maintained in previous comments to the agency that the vast majority of consumers with 20/50 or better corrected vision, which represent about 950/0 of American consumers, can read type sizes down to and including 4,5 point type (i.e., the minimum allowed on food labels), we believe that label requirements should seek to optimize the ability of companies to use the largest type size reasonable in the presentation of required label information.
2. Most dietary supplements are not used on a per day basis in large multiples, but rather most often on the basis of two to three times per day. Thus, a paragraph listing of "Recommended Servings Per Day (insert amount)" would specify a per day amount that could easily be used to calculate the total per day amount based on the "per unit" column

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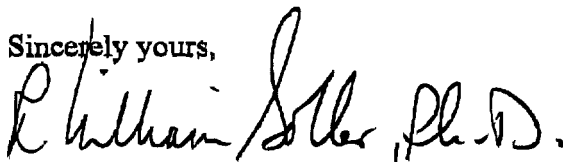
of **information**. Including **a phrase** such as “(multiply per **caplet amounts** by (insert the number of per day servings) **for per day amount**)” **under the** “Per Unit” Heading explicitly instructs the **consumers** on how **to define** the **total per day amount**.

3. **The** proposed paragraph listing **allows** a simple **and logical** calculation that **can** be **done** by the vast majority, if not all, of those with at least a fourth **grade** education.
4. With the emphasis on **label** claims for dietary Supplements, **including** FDA approved health **claims** and the health **claims based** on statements from authoritative bodies, **the** dietary supplement **label** is becoming increasingly enlarged by **the addition of** important and useful product use information. Therefore, FDA should **seek** ways **to balance the** potentially conflicting public health **needs** of the presentation of all **of the** needed and required **information** and the limited **label** space of **dietary** supplement product labels. **As** a result, FDA **should seek** to create a regulation allowing **voluntary** use **of** per Day information in away that optimizes use **of the larger type sizes**, where reasonable and feasible. The use of **a column format would** increase **the Supplement** Facts box by about 30%, thereby potentially **driving** the choice **of type size to the** minimum **required to** offset the additional space consumed by a larger supplement **facts** box. This is not necessarily in **the public** interest,

**Thus**, allowing the total per day amount to be expressed **in either** paragraph **form** -to offset the additional space consumed by **a** larger supplements facts box - or in **column** format, would **permit companies** to optimize **type size of** dietary supplement labels for even better label readability,

In conclusion, **CHPA** supports the agency’s proposal to **permit** the inclusion **of** “Per Day” **information** on **the** dietary **supplement label**, at the discretion of the **manufacturer**, and **offers** a specific recommendation **to help optimize** the label readability **of** dietary supplements in those cases where the addition of such information, which could create approximately a 300/e increase **in the** size of **the** Supplement Facts box, **would** potentially drive the choice of type size **to the** minimum **size** required **by** regulation.

Sincerely yours,



R. William Soiler, Ph.D.  
Senior Vice President and  
Director **of** Science & Technology

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